



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/359,260	07/22/1999	ROBERT L. CAMPBELL	P3250	2590

26253 7590 04/11/2005

DAVID W. HIGHET, VP AND CHIEF IP COUNSEL
BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE, MC 110
FRANKLIN LAKES, NJ 07417-1880

EXAMINER

DEJONG, ERIC S

ART UNIT PAPER NUMBER

1631

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/359,260

Applicant(s)

CAMPBELL ET AL.

Examiner

Eric S. DeJong

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2004 and 16 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73, 76 and 82-134 is/are pending in the application.
- 4a) Of the above claim(s) 1-73 and 96-127 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 76, 82-95 and 128-134 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicants traversal arguments of the restriction and species elections, mailed on 4/21/2004, has been fully considered and is found convincing. As such, the Examiner has withdrawn restriction and species election from the previous Office Action, mailed on 4/21/2004.

ACKNOWLEDGMENTS

Applicants arguments, filed on 12/16/2004, are relied upon for the basis of this Office Action. It is acknowledged that applicants requested consideration of the documents filed on 9/10/2004, however upon further review of said documents it was discovered that the remarks are identical to those contained in the arguments filed 12/16/2004. As such only the latter filed arguments have been considered.

Applicants' arguments, filed 12/16/2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 74 and 77-81 have been canceled. Claims 1-73 and 96-127 are withdrawn from consideration. Claims 76, 82-95, and 128-134 are under examination in the instant application.

TITLE

The title of the invention is not descriptive. The title of the instant application, "Methods, Apparatus, and Computer Program Products for Formulating Culture Media", does not clearly reflect the broad scope of the instant claimed invention which is now directed to methods of identifying a peptide with a desired activity. A new title is required that is clearly indicative of the invention to which the claims are directed.

Withdrawal of Utility Rejection Under 35 U.S.C. § 101 and 112

Applicants arguments directed toward the utility of the claimed invention as well as amendments to the instant claims are found convincing and, therefore, the previously presented rejections on the basis of utility are hereby withdrawn.

Withdrawal of Written Description Rejection Under 35 U.S.C. § 112

Applicants arguments directed toward the written description provided by the instant disclosure as well as are found convincing and, therefore, the previously presented rejections on the basis of a lack written description are hereby withdrawn.

Withdrawal of Vague and Indefinite Rejection Under 35 U.S.C. § 112

Applicants arguments directed toward vagueness and indefiniteness of terms used in the instant claims are found convincing and, therefore, the previously presented rejections on the basis of vagueness and indefiniteness of terms used in the instant claims are hereby withdrawn.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 76, 82-93, 95 and 128-134 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

NEW MATTER has been amended into the instant claims via several limitations.

Claim 128, lines 3 and 5, recites the limitation of constructing a first peptide library "wherein the length of said first test peptides comprises no greater than 20 amino acids". Consideration of the instant specification and claims as originally filed has failed to reveal specific and direct support for a first peptide library wherein the range of the first test peptide lengths are restricted to no greater than 20 amino acids. It is acknowledged that the instant specification cites several preferred embodiments for a peptide library, and on page 25, lines 28-30, a preferred embodiment is recited wherein peptides have "a length in a range from about four to about twenty amino acids, more preferably from about four amino acids to about ten amino acids". However, these preferred embodiment is not identical to the range of first peptide lengths as presented in the instant claim and there is therefore NEW MATTER. Claims 76, 82-93, 95, and 129 are also included under this rejection due to their dependence from claim 128.

Claim 129, lines 2-5 contain the limitations of "selecting a subgroup of the first test peptides" and "expanding said first test peptides from said subgroup into their constituent compound isomers". Consideration of the instant specification has failed to reveal any specific or direct support for combining the method steps as recited in instant claims 128 with the above limitations of selecting a subgroup of first test peptides and further expanding the first test peptides into constituent compound isomers. Since no antecedent basis from the instant specification or claims as originally filed has been provided, the above recited limitations from claim 129 therefore represent **NEW MATTER**.

Claim 130, line 3 contains the limitation "identifying initial peptides having a length no greater than twenty amino acids". The claim further recites selecting a plurality of said initial test peptides to form a first library. Consideration of the instant specification has failed to reveal specific and direct support for a first peptide library wherein the range of the first test peptide lengths are restricted to no greater than 20 amino acids. It is acknowledged that the instant specification cites several preferred embodiments for a peptide library, and on page 25, lines 28-29, a preferred embodiment is recited wherein peptides have "a length in a range from about four to about 20 amino acids". However, this preferred embodiment is not identical to the range of first peptide lengths as presented in the instant claim and there is therefore **NEW MATTER**. Claims 131-134 are also included under this rejection due to their dependence from claim 130.

Art Unit: 1631

Claim 133, lines 1-3 contains the limitation "prior to said step of selecting, a step of adjusting said test requirement by a desired value for improving results of said step of selecting a new second peptide library". Consideration of the instant specification has failed to reveal specific and direct support for a an additional step of adjusting a test requirement prior to the step of selecting as presented in the method of instant claim 130. Since no antecedent basis from the instant specification or claims as originally filed has been provided, the above recited limitation from claim 133 therefore represents **NEW MATTER**.

The above rejections pertaining to **NEW MATTER** are necessitated by amendment to the instant claims.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 76, 82, 83, 87, 92-95, and 128-134 are rejected under 35 U.S.C. 102(b) as being anticipated by Ostrem et al. This rejection is necessitated by amendment to the instant claims.

Applicants assert that Ostrem et al. does not disclose specific steps such as the determination of a relationship between indicia and at least two parameters from a single library of peptides. Further, applicants assert there is no disclosure or suggestion in Ostrem et al. for determining a relationship.

Art Unit: 1631

Claims 76, 95, 96, 128, 130, and 131: Ostrem et al. discloses procedures for the preparation of a combinatorial octamer test peptide library (constructing a first peptide library; identifying initial peptides; first test peptides contain no greater than about twenty amino acids; no greater than 10 amino acids, no less than about 4 amino acids). See Ostrem et al., at least Abstract and page 1054, column 1, first paragraph. Determining a peptide length of 8 amino acids reads on the claimed characterizing first test peptides by a first parameter that is a sequence-specific parameter and the claimed selecting a plurality of peptides is performed using a space-filling design that applies a distance function (broadly interpreted as peptides are selected as 8 amino acids in length). Determining that the library is comprised of a combinatorial peptides reads on the claimed characterizing first test peptides by a second parameter that is a whole molecule parameter. The ability of test peptides to bind to factor Xa reads on the claimed measuring the indicia of an activity a plurality of first test peptides. See Ostrem et al., at least page 1054 first paragraph and page 1055 second paragraph. The ability of test combinatorial peptides 8 amino acids in length to bind to factor Xa reads on the claimed determination of a relationship between said indicia of said activity, said first parameter, and said second parameter. The initial leads identified in said octamer combinatorial peptide library ranged in potency increased from 4 to 15 μ M and reads on the claimed calculating an estimated indicia for each first test peptide in said first test peptide library using said determined relationship. See Ostrem et al., at least Abstract and page 1055, column 1, last bridging paragraph through column 2, first bridging paragraph and Figure 1. Also, the above testing performed the octamer combinatorial

Art Unit: 1631

peptide library for changes in potency reads on the claimed setting a test requirement, based on activity, having a test indicia range. Identifying a subset of the first peptide library and, based upon their ability to bind factor Xa, using the peptides in a prothrombinase assay reads on the claimed identifying a second test peptide library. See Ostrem et al., at least page 1055, table 1. The identified subset of the first peptide library was measured against the ability to bind factor Xa and meets the claimed determining the indicia of said at least one second test peptide and identifying at least one second test peptide having an indicia that satisfies said test requirement.

Under a reasonably broad interpretation, evaluating the potency of the octomer combinatorial peptides reads on determining a relationship comprising the step of determining $y_i = f(x_{ij})$, wherein potency is the whole molecule parameter X_{ij} , i represents the number representative of octomer peptide tested, j ranges from 1 to d , and d is 1 as only one whole molecule parameters is evaluated, and y_i represents potency, the activity being determined for each octomer combinatorial peptide.

Claim 129, 132, and 134: The library screening procedure discloses that multiple peptide libraries were constructing in accordance with the above described procedures and there each library. As such, all peptides utilized in the peptide libraries can be construed to be a first peptide library under a reasonably broad interpretation that reads on the above described method steps. Further each peptide library can be taken individually as a second, under a reasonably broad interpretation, and therefor reads on a the claimed selection of a subgroup of first test peptides, from said test peptides, having an indicia that satisfies said test requirements. Segregation of all test peptides in

Art Unit: 1631

their entirety into separate peptide libraries and then further identifying subsets of each library reads on the claimed expanding said first test peptides from said subgroups into their constituent compound isomers using a space filling design as well as the claimed repeating said steps of selecting a new plurality of peptides, determining a new relationship, calculating an estimated indicia, and selecting a new second test peptide library until the number of initial peptides in said new second test peptide library does not exceed the predetermined threshold.

Claim 82: The Identifying a subset of the first peptide library and, based upon their ability to bind factor Xa, using the peptides in a prothrombinase assay reads on the claimed space-filling design expands less than all of the first test peptides into their constituents.

Claim 87 and 93: The ability of test peptides to bind to factor Xa reads on the claimed activity of binding to a receptor and the claimed activity is inducement of activation of a receptor.

Claim 92 and 133: Part of the disclosed library screening process includes the step of incubating destained beads with the factor Xa-SAP-inhibitor mixture. See Ostrem et al., page 1054, column 1, first paragraph. The determining activity can be broadly construed as peptides being exposed to the incubation process with the inhibitor mixture and therefor reads on the claimed inhibition of activation of a receptor. Further, the step of incubation reads on a sep of adjusting said test requirement by a desired value for improving results of said step of selecting a new second peptide library.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tenson et al. reads on a majority of the limitations contained in the instant claims, but the art is consonant with the basis of the prior art rejection presented for Ostrem et al.

Art Unit: 1631

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 272-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDJ

EDJ

John S. Brusca 7 April 2005

JOHN S. BRUSCA, PH.D.
PRIMARY EXAMINER